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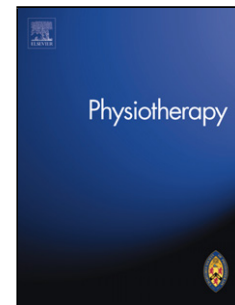
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Physiotherapy for primary frozen shoulder in secondary care: Developing and implementing stand-alone and post-operative protocols for UK FROST and inferences for wider practice

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N.C.A. Hanchard: Input into all aspects of methods, Delphi survey development, implementation and analysis; wrote the paper. ☐

L. Goodchild: Input into Delphi survey development, implementation and analysis; revision of manuscript.

S. D. Brealey: Input into Delphi survey development, implementation and analysis; revision of manuscript. ☐

SE. Lamb: revision of manuscript. ☐

A. Rangan: Chief investigator UK FROST; advice on content; revision of manuscript.

Ethics approval

Delphi survey ethics approval Ethics approval (069/14) for the Delphi survey was obtained from the School of Health and Social Care Research Governance and Ethics Committee of Teesside University on 23rd May 2014.

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Conflicts of interest

Dr Rangan's department has received educational and research funds from DePuy Ltd outside the submitted work. None of the other authors declare any conflicts.

**Physiotherapy for primary frozen shoulder in secondary care:
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Abstract

Objectives The United Kingdom Frozen Shoulder Trial (UK FROST) compares stand-alone physiotherapy and two operative procedures, both with post-operative rehabilitation, for primary frozen shoulder in secondary care. We developed physiotherapy protocols for UK FROST, incorporating best evidence but recognizing uncertainty and allowing flexibility.

Methods We screened a UK Department of Health systematic review and UK evidence-based guidelines^{1,2} for recommendations, and previous surveys of UK physiotherapists^{3,4} for strong consensus. We conducted a two-stage, questionnaire-based, modified Delphi survey of shoulder specialist physiotherapists in the UK National Health Service. This required positive, negative or neutral ratings of possible interventions in four clinical contexts (stand-alone physiotherapy for, respectively, predominantly painful and predominantly stiff frozen shoulder; and post-operative physiotherapy for, respectively, predominantly painful and predominantly stiff frozen shoulder). We proposed respectively mandating or recommending interventions with 100% and 90% positive consensus, and respectively disallowing or discouraging interventions with 90% and 80% negative consensus. Other interventions would be optional.

Results The systematic review and guideline recommended including steroid injection and manual mobilizations in non-operative care, and we mandated these for stand-alone physiotherapy. Consensus in the pre-existing surveys strongly favoured advice, education and home exercises, which we mandated across contexts. The Delphi survey led to recommendation of some supervised exercise modalities, plus the disallowing or discouragement—in various contexts—of immobilization and some ‘higher-tech’ electrotherapies and alternative therapies.

Conclusions We developed physiotherapy protocols despite incomplete empirical evidence. Their clear structure enabled implementation in data-sheets designed to

facilitate recording, monitoring of fidelity and reporting of interventions. Other trials involving physiotherapy may benefit from this approach.

Contribution of the paper

- Pre-existing reviews and guidelines^{1,2} for use of physiotherapy in treatment of primary frozen shoulder confirmed that the empirical evidence was very limited: only steroid injections and manual mobilization, both for non-operative care, were recommended. Previous surveys^{3,4} emphasized patient advice, education and provision of home exercises as key elements of care.
- A dedicated Delphi survey helped develop physiotherapy protocols to be used in all three arms of the United Kingdom Frozen Shoulder Trial (UKFROST), comparing stand-alone physiotherapy and two operative procedures, both with post-operative rehabilitation, for primary frozen shoulder.
- Our approach lends itself to the development of structured protocols, enabling implementation in data-sheets that facilitate recording, monitoring of fidelity and reporting of interventions in clinical trials.

Key words

Frozen shoulder, methods, physiotherapy, protocol, UK FROST

Introduction

Primary frozen shoulder has a prevalence of around 10% in the general population⁵ and causes profound physical and emotional effects.⁶ It is idiopathic, and starts with pain in the shoulder and arm,⁷ which increases as stiffness develops. The pain and stiffness may become severe, causing substantial functional impairments.^{6,7} There is a tendency to resolution, but the natural history is protracted, spanning months or years, and recovery may be slow or incomplete.⁸ Patients' anxieties are fuelled by uncertainties about their diagnosis, the likely outcome or both, against a background of chronic pain and disturbed sleep.⁶

For patients entering secondary care with primary frozen shoulder, popular treatments in the UK National Health Service (NHS), include: physiotherapy

(permutations of advice, exercises, therapist-applied mobilization techniques and thermo- and electrotherapies); intra-articular steroid injection(s), which many NHS physiotherapists are trained to administer; manipulation under anaesthetic (MUA), repeated if symptoms recur,⁹ which may be combined with a steroid injection (MUA with steroid); and arthroscopic capsular release (ACR), supplemented by MUA (ACR with MUA).¹⁰ However, it is unknown whether a combination of steroid injection and physiotherapy (steroid with PT) or either of the operative procedures, each with post-operative physiotherapy, is more effective.² UK FROST is a multi-centre randomized controlled trial (RCT) that seeks to clarify this at the point in the care pathway when an operative procedure is being considered. It compares steroid with PT *versus* MUA and steroid with PT *versus* ACR and MUA with PT. Crucially, all arms of UK FROST involve physiotherapy, either as part of the stand-alone physiotherapy intervention (designated as 'structured physiotherapy' in the trial) or as rehabilitation following an operative procedure ('post-procedural physiotherapy').

We aimed to rationalize development and implementation of the physiotherapy protocols in UK FROST, so as to make the interventions relevant and acceptable beyond the trial. This would involve:

- developing physiotherapy protocols that would incorporate 'best practice' insofar as this could be established, while recognizing uncertainty and accommodating clinical adaptability;
- implementing these protocols as graduated models for stand-alone and post-operative physiotherapy, whereby any possible physiotherapy intervention would fall into one category on an ordinal scale of 'mandatory', 'optional' or 'not allowed'; and
- gauging the optimal duration of a course of physiotherapy based on clinical considerations.

In operationalizing the protocols, we further aimed to develop data collection forms that would facilitate:

- adherence by trial physiotherapists;
- quick, comprehensive documentation of treatments; and ultimately
- comprehensive reporting as recommended by the TiDIER guidelines.¹¹

While UK FROST motivated these processes, we anticipated that the results would allow us to cautiously draw more general inferences.

Methods

The research team explicitly established *a priori* three fundamental and non-negotiable standards for the conduct of physiotherapy in the trial. These were that it should be delivered only by qualified physiotherapists and only in hospital settings (to ensure accessibility of resources), and that post-operative physiotherapy should ideally commence within 24 hours of the procedure. We established, too, that treating physiotherapists would be required to document their grade, as well as the number of frozen shoulder patients typically treated in their routine practice.

We then compiled a list of broadly defined, potentially applicable physiotherapy interventions from the general literature and discussion and set out to categorize each on our ordinal scale. Ideally, we based these categorizations on empirical evidence (from evidence-based clinical guidelines and systematic reviews of RCTs and economic evaluations) but, if this was unavailable, on existing, published expert consensus or a Delphi survey of shoulder-specialist physiotherapists that was conducted especially for UK FROST. Each intervention had to be categorized in four clinical contexts (Figure 1), which accounted for whether physiotherapy was stand-alone or post-operative and whether the presentation was ‘pain-’ or ‘stiffness-predominant’. The latter dichotomy, which is meaningful to clinicians and patients, was developed originally for non-operatively managed frozen shoulder,^{3,4} but we reasoned that it would also apply post-operatively.

Evidence-based clinical guidelines and systematic reviews of RCTs We drew on primary RCTs and economic analyses through two resources previously developed by our group: the UK national physiotherapy guidelines for frozen shoulder, which were based on a systematic review;^{1,12} and a systematic review and cost-benefit analysis commissioned by the National Institutes for Health Research (NIHR) Health Technology Assessment (HTA) programme.² These rigorously evaluated the effectiveness of many applicable physiotherapy interventions (including steroid injection) and detailed the scheduling and duration of physiotherapy in any studies that showed benefit.

Our reviews^{1,2,12} revealed no good-quality RCTs or economic analyses on post-operative physiotherapy. We therefore expanded our scope to include the *GOST: Shoulder and Elbow Guidance for Orthopaedic Surgeons and Therapists*,¹³ particularly to inform the overall duration of our post-operative physiotherapy programmes. This

document represents the generally accepted UK standard for post-operative physiotherapy care.

Expert consensus Expert consensus was derived from two previous questionnaire surveys on UK physiotherapists' approaches to stand-alone physiotherapy for frozen shoulder,^{3, 4} from which we extrapolated to post-operative care if this was reasonable, and a Delphi survey of UK shoulder specialist physiotherapists, which addressed stand-alone and post-operative physiotherapy.

Delphi survey This was a modified Delphi survey conducted in two rounds. The target population was NHS shoulder specialist physiotherapists and the sampling frame was the contact physiotherapists for three major shoulder RCTs recently conducted in the NHS: CSAW,¹⁴ ProFHER¹⁵ and UKUFF.¹⁶

Development of the Delphi survey Two authors, NH and LG, both shoulder specialist physiotherapists (one academic and one clinical) developed a list of potentially relevant treatment interventions, erring towards over-inclusivity (Table 1). This list was used to populate a Delphi questionnaire in which respondents would be required to categorize the respective interventions as 'should always be used' (i.e. mandatory), 'should not be used' (not allowed) or 'optional' in each of the four study contexts (Figure 1). Certain interventions were pre-categorized, based on recommendations of the evidence-based clinical guidelines and HTA systematic review,^{1,12} on strong, previously established expert consensus,^{3, 4} or both (italicized items in Table 1, and see Results). The questionnaire explained these exceptions, and did not require respondents to categorize them. Spaces were provided for respondents to add any unlisted treatment interventions that they thought important.

Round two questionnaires replicated those of round one, but reminded respondents of their respective round-one categorizations as well as presenting the modal categorizations for all respondents. Thus individual responses were informed by those of the group and could be modified at this stage.

The objectives of the Delphi study were to achieve consensus and to quantify the level of agreement. We did not require criteria to determine when to stop the Delphi because we structured the survey to deliver the best possible consensus over 2 rounds. Consensus criteria are listed in Table 2.

Piloting of the questionnaires by 10 physiotherapists (seven clinical and three academic) resulted in addition of a 'don't know' option for categorizations, but no other changes, and indicated that the round one questionnaire could be completed in 20 minutes or less and round two in 25-30 minutes or less. The definitive questionnaires were implemented on protected Word® forms.

Delphi survey recruitment strategy A 'gatekeeper' approach was used. One of us (AR) knew the site Principal Investigators (usually surgeons) of CSAW, ProFHER and UKUFF, and emailed each of them (N = 113) to ask that they forward the email to the most appropriate physiotherapist at their site. We estimated that the sampling frame comprised between 70 and 100 physiotherapists.

Delphi survey procedure The email incorporated the covering letter for the invitations to participate and, as attachments, the Participant Information Sheet and the first round questionnaire. This email informed the Principal Investigators of our intention to send routine reminders through them to the potential participants one and two weeks hence, and asked that those emails be forwarded in the same way. Round one questionnaires required respondents to provide their names and preferred email addresses, while round two required names. These data enabled: matching of round one and two questionnaires; emailing of round two questionnaires directly to participants rather than *via* 'gatekeepers'; feedback of the survey results; and entry of participants who had completed and returned both questionnaires into a prize draw for a £50.00 shop voucher. Up to two weekly reminders were sent for round two.

Delphi survey analysis Table 2 shows the implementation of Delphi consensus thresholds in the development of the UK FROST protocol. We decided *a priori* that a 90% consensus of valid respondents who expressed an opinion was convincing. We duly disallowed interventions with a $\geq 90\%$ rating of 'should not be used' from UK FROST. However, we could not apply a corresponding consensus threshold to 'should always be used' to define mandatory interventions. This would have risked labelling as mandatory certain interventions that some centres could not deliver, due to lack of facilities, equipment or specific skills. Pragmatism therefore dictated that consensus for 'should always be used' be set at 100% of valid responders who expressed an opinion. We defined interventions that met neither the 'should always be used' nor the 'should not be used' thresholds as 'optional'. Furthermore, we retrospectively decided that, to make best use of our data, we would stratify the 'optional' category. This involved

setting secondary, 80% levels of consensus for ‘should always be used’ and ‘should not be used’. These would be respectively implemented as ‘recommended’ and ‘discouraged’ interventions in the protocol.

Lastly, as well as informing the UK FROST protocol, we aimed to make our data directly useful to clinical physiotherapists. This involved a supplementary analysis redefining consensus as > 50% of valid respondents. We selected > 50% for this purpose because, as the threshold for the pronoun ‘most’, it is an intuitive and universally meaningful quantification. Specifically, given the paucity of evidence, we considered that clinicians could gain much reassurance from an indication of how most of our expert respondents rated each of the interventions. In the clinical setting, this level of quantification would provide a more useful benchmark than the 80-90% required for developing the UK FROST protocol. As valuable as such inferences for clinical practice may be, however, they are only indicative. This is because they reach beyond the frame of the Delphi survey, which was couched in the context of UK FROST. We briefly present this aspect of our analysis in our paper, but further details are provided in the [supplementary information](#).

Results and their application

Evidence-based clinical guidelines and systematic reviews of RCTs Our reviews^{1,12} revealed that good-quality empirical evidence for or against effectiveness was very limited, and that there was none applicable post-operatively. For conservatively managed frozen shoulder both documents had, however, recommended steroid injection and adjunctive manual mobilizations. These recommendations were based on two RCTs—one in secondary care and at low risk of bias,¹⁷ the other in primary care and at some risk of bias,¹⁸ which collectively provided moderate evidence that a steroid injection is effective for conservatively managed frozen shoulder, and that physiotherapist-applied manual mobilizations, adapted to suit differing clinical presentations, might augment the benefit for some outcomes. We therefore specified that a steroid injection (unless clearly not indicated or contra-indicated) ‘should always be used’ as part of structured physiotherapy, as should physiotherapist-applied manual mobilizations. However, recognizing that there are many different approaches to manual mobilisations, all influenced by patient presentation, we did not prescribe the technique or insist that they be given at every session.

A further consideration was the number and distribution of sessions. Our primary sources^{17,18} provided nine and twelve physiotherapy sessions respectively, but distributed them differently (Table 3). We emulated the higher figure but approached distribution pragmatically, specifying that sessions could be spaced and used at physiotherapists' discretion over up to 12 weeks. Where progress required fewer sessions, this was acceptable. We did not prescribe the length of each session. We applied a similar structure to post-operative physiotherapy delivery. This was commensurate with the recommendation in *GOST: Shoulder & Elbow* that post-operative physiotherapy for ACR should be continued for up to 12 weeks. *GOST: Shoulder & Elbow* did not address MUA as an isolated procedure.¹³

Expert consensus

Existing literature Previous surveys of UK physiotherapists involved in treating frozen shoulder^{3, 4} revealed that a very large majority favoured provision of advice, education and exercises. We therefore pre-specified "advice and education" and "home exercises" as mandatory elements of the stand-alone physiotherapy protocol and confidently extrapolated this mandatory status to post-operative physiotherapy. We were unable to provide evidence for specific exercises or dose however, and determined that these would be delivered throughout the trial on an individual basis according to clinical judgment.

Delphi survey There were 46 responses to round one (41% response rate) and 42 to round two, demonstrating good retention (91%). For one round two respondent, some responses were void. Forty-five round one respondents (98%) were self-reportedly shoulder specialist physiotherapists. The detailed results of the Delphi survey are shown in Figures 2 to 5. These are considered in relation to UK FROST and then, briefly, more generally. The latter aspect is addressed more extensively in the [supplementary information](#).

No interventions achieved the 100% consensus criterion for 'should always be used' in UK FROST, but some, all exercise-related, reached or exceeded 80%, and were therefore 'recommended' (Figures 3 to 5). These were one-to-one function-based exercises for structured physiotherapy in the stiffness-predominant phase, one-to-one gentle active exercises for post-operative physiotherapy in the pain-predominant phase, and one-to-one gentle active exercise and function-based exercise for post-operative physiotherapy in the stiffness-predominant phase.

Some interventions met or exceeded our 90% consensus criterion for 'should not be used' and were consequently disallowed by the UK FROST protocol. In this category, and applicable to all four of the clinical contexts, were deep friction, laser and provision of a brace. There was also $\geq 90\%$ consensus that craniosacral therapy, interferential and shockwave therapy 'should not be used' in the stiffness- predominant phase for either structured or post-operative physiotherapy when stiffness was the predominant problem; and that craniosacral therapy 'should not be used' for structured physiotherapy in the pain-predominant phase. A number of interventions met or exceeded our 80% consensus criterion for 'should not be used' in one or more of the four clinical contexts, and the protocol discouraged their use in those contexts. Thus ultrasound was discouraged in all contexts; Bowen therapy in all contexts except structured physiotherapy during the stiffness-predominant phase; graded motor imagery, mirror therapy and shortwave diathermy for stiffness-predominant presentations, irrespective of whether the physiotherapy was structured or post-operative; shockwave therapy for structured physiotherapy in the pain-predominant phase; and craniosacral therapy and electro-acupuncture for post-operative physiotherapy in the pain- and stiffness-predominant stages, respectively. Most interventions considered in the Delphi survey fell short of 80% consensus for 'should always be used' and also for 'should not be used'. These were all allowed by the UK FROST protocol.

As previously stated, to cautiously apply our results more generally, we performed a supplementary analysis in which we re-defined consensus as a simple majority. There is no compelling reason to suppose that respondents would have rated interventions any differently for applications outside of UK FROST. Nonetheless, the fact remains that ratings were made for the latter, and extrapolation from that context can only be indicative. Refer to the [supplementary information](#) for more detailed narrative on this aspect. Briefly, at this level of consensus, most interventions were considered at least acceptable. The cluster of interventions categorized as 'should always be used' expanded by gaining additional types of exercise, as well as postural re-education, across clinical contexts. At the other end of the spectrum, additional interventions rated as 'should not be used' across all four contexts most notably included the most 'alternative' therapies, higher-tech electro- and thermotherapies, graded motor imagery, mirror therapy and provision of a brace. As would be expected, the majority of

respondents also rated most analgesic modalities and strategies as ‘should not be used’ in the stiffness-predominant stage.

Operationalising the results of the reviews and expert consensus for UK FROST

Our rational approach to developing the physiotherapy protocols in UK FROST was a crucial step towards making the interventions relevant and acceptable beyond the trial. But in operationalizing these there were two other key considerations. First, the data collection instrument had to capture interventions in sufficient detail to enable comprehensive reporting as recommended by the TiDIER guidelines¹¹ and be navigable by clinicians and researchers alike. Second, in order to optimize participating physiotherapists’ adherence and the reliability of their recording, it had to be clearly presented and quick and easy to complete, requiring little more than routine record keeping.

We developed two log sheets, one for structured physiotherapy sessions and one for post-operative physiotherapy sessions (Figures 6 and 7 in the [supplementary information](#)), which were collated into patient-specific logbooks. The log sheets served as *aides-memoire* and forms for quickly documenting key session characteristics. Each required a judgment as to whether, on that particular day, pain or stiffness predominated. The physiotherapist was then directed to a corresponding column on the form. This listed the interventions that were disallowed or discouraged for clear reference. It specified and highlighted the interventions that were mandatory or encouraged in a tick box format to facilitate recording. To further enhance the ease of recording, the checkbox lists were extended to include a limited number of additional interventions that we expected to be frequently used, these being derived from the remaining Delphi items with the highest levels of acceptability (the ‘should always be used’ and ‘should be optional’ categories combined). This last process involved screening out broadly equivalent terms to avoid redundancy, and clustering highly related interventions provided that doing so would not cause confusion, that the interventions’ acceptability was high and homogeneous, that there was clinical justification, and that any clustered data were sufficient for our research aims. Such judgements were made on a context specific basis. There was no requirement for physiotherapists to use any of these additional interventions, which were provided only for ease of recording; and they were free to use any others, unless they were disallowed

or—to a lesser degree—discouraged. Space was provided for other interventions to be recorded in longhand.

Discussion

We used composite methodology to evaluate a wide range of physiotherapy interventions for stand-alone (structured) and post-operative physiotherapy for primary frozen shoulder. This was mainly motivated by the requirement to develop ‘best practice’ physiotherapy protocols for UK FROST. Standardization of complex interventions like physiotherapy in clinical trials is problematic, because empirical evidence is patchy, opinions differ, and different contexts may demand different approaches. Rigid standardization may over-reach from the evidence, fail to accommodate contextual factors, alienate clinicians and patients—and possibly impact upon outcomes—by limiting choice and adaptability, and lack relevance to real-life practice. Conversely, inadequate standardization may lead to trial treatment provision that is un-evidenced, hard or impossible to define, and not replicable.¹⁹ Clearly, in trials such as UK FROST, a position between these extremes, which respectively characterize explanatory and pragmatic research, would be desirable. In practice, this has seldom been achieved: a recent, large systematic review of surgical trial interventions (comparably complex to interventions in physiotherapy trials) revealed that fewer than one third were reportedly standardized, and fewer than one third were monitored for adherence, regardless of whether the trials were claimed to be explanatory or pragmatic.²⁰ The design, conduct, monitoring and reporting of rehabilitation in surgical trials has been particularly poor, but the recent ProFHER (Proximal Fracture of Humerus Evaluation by Randomisation) trial, a surgical trial with a physiotherapy intervention group, set foundational standards in these regards.²¹ They used paper-based (thus universally available) forms listing the likeliest interventions alongside tick boxes, and provided space in which other interventions could be recorded longhand. Their forms were well completed,²¹ and we sought to replicate their properties. Listing all of the interventions derived from empirical evidence, established best practice and the Delphi survey was an option; but these would have numbered 50 or more per context, making the forms cumbersome and burdensome to use, not least because many of the Delphi items were not mutually exclusive. A further option now available would be electronic data collection. Electronic note keeping has become common since the

inception of UK FROST, and data collection could readily be ported to that medium; but the same limitations apply. In order to achieve proper balance in our own trial, we identified possible physiotherapy interventions and classified them as 'mandatory', 'recommended', 'optional', 'discouraged' or 'not allowed', according to available empirical evidence, clinical guidelines or expert opinion, as applicable. Alongside guidance on the number and distribution of physiotherapy sessions, this provided a clearly defined treatment framework, and facilitated monitoring of treatment fidelity as well as recording of the interventions given. This approach is broadly commensurate with the strategy for standardizing complex surgical interventions that has subsequently been recommended.²²

On implementing our approach, we could derive only limited data from existing empirical evidence and/or clinical guidelines. This informed the number and distribution of treatment sessions in UK FROST (stand-alone and post-operative physiotherapy) and enabled us to designate a small number of core interventions (for stand-alone physiotherapy only); but the dearth of data placed a premium on our Delphi survey, in which responders were free to consider all but a handful of pre-stated core interventions. Applying our stringent consensus criteria (Table 2) to further inform the physiotherapy protocols for UK FROST, no intervention reached the pre-specified consensus threshold to be deemed mandatory; while few reached the thresholds at which to be encouraged, discouraged or disallowed. Most interventions were therefore categorized as optional. It is noteworthy that even among this sample of shoulder-specialist physiotherapists there was only a single instance of complete consensus. This highlights the level of uncertainty that exists.

Our Delphi respondents were asked to rate interventions specifically in the context of UK FROST, and our rather stringent criteria for consensus were set with that in mind. However, as a supplementary step, we re-analyzed the Delphi survey using a less stringent criterion (>50%) for consensus as to whether interventions 'should always be used', either 'always be used' or 'optional' in combination (i.e. at least acceptable), or 'should not be used'. This was to increase the relevance of our paper to clinical physiotherapists, for whom the weight of expert opinion may seem more relevant than the high consensus thresholds used in developing UK FROST. Viewed in these terms, the Delphi survey revealed a relatively small nucleus of interventions (approximately 5 to 10%, according to context) that were favoured. More (approximately 25-50%) were

considered unacceptable; and more still (approximately 40 to 70%) were rated as at least acceptable options. The distribution broadly agrees with our previous single-round questionnaire surveys,^{3, 4} although those surveys did not include post-operative physiotherapy. To our knowledge, no previous study has sought physiotherapists' opinions on the post-operative rehabilitation of frozen shoulder.

Limitations With only a 41% response rate and 46 participants the Delphi survey may not represent the majority of clinical opinion. Higher response rates are desirable but prove difficult to achieve. We offered the opportunity to win a high street voucher as an incentive, and purposefully made involvement with the Delphi process as straightforward as possible both to maximize participation and—anticipating that *most participants would also be asked to take part in to UK FROST itself—to minimize respondent fatigue*. To these ends we developed the survey to achieve consensus and quantify the level of agreement in just two rounds. *Two rounds are relatively few but were expected to be sufficient for the purposes of protocol development; and, though possible, it is doubtful whether further rounds would have substantively altered the consensus that most interventions should be optional.*

While our supplementary analysis of the Delphi data using the >50% level of consensus increases the relevance of our paper to clinical physiotherapists, the fact remains that the Delphi respondents were asked to rate the interventions for UK FROST specifically, and so due caution must be exercised when extrapolating the results to wider practice.

Conclusions

We used a composite methodology to inform stand-alone and post-operative physiotherapy interventions in UK FROST, which is comparing injection with physiotherapy; and two surgical options with physiotherapy for primary frozen shoulder in secondary care. This facilitated development of a structured, flexible protocol that reflects best evidence but recognizes uncertainty and variations in preference, expertise and context. In implementing the protocol, we sought to optimize recording, monitoring and reporting of the physiotherapy interventions. Supplementary analysis of the Delphi survey, cautiously extrapolating beyond UK FROST, revealed a picture in which most interventions were at least acceptable, but exercises were

generally favoured; and immobilization, higher-tech electrotherapies and most alternative therapies were generally viewed negatively by shoulder specialist physiotherapists in the UK.

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Table 1. Interventions considered in the Delphi questionnaires (including those added by respondents). Pre-specified mandatory interventions for UK FROST are shown in italics, where † is based on empirical evidence and ‡ on our previous questionnaire surveys; *PT* applies to stand-alone physiotherapy, *Post-op* to post-operative physiotherapy, *Pain* to pain- predominant and *Stiff* to stiffness-predominant.

Category	Intervention
Education and re-education	<i>Advice and education (‡, PT, (Post-op), Pain, Stiff)</i>
	Alexander technique
	CBT
	Explain pain
	Graded motor imagery
	Mirror therapy
	Posture re-education
	Relaxation techniques
Injection	<i>Intra-articular steroid injection (†, ‡, PT, Pain)</i>
Hands-on techniques	<i>Manual mobilisations (†, ‡, PT, Pain, Stiff)</i>
	Bowen therapy
	Craniosacral therapy
	Effleurage for pain
	Mobilisations with Movement (MWMs)
	Muscle energy techniques
	Myofascial release
	PNF
	Spinal/scapulothoracic manual therapy
	Therapist-assisted end range mobilisations
	Tool-assisted soft tissue techniques
Exercises	1-to-1 function based exercises
	1-to-1 gentle active exercises
	1-to-1 sustained stretching exercises
	Active assisted exercises with scapula control
	Facilitation/strength training of rotator cuff/scapula
	Gentle pulley exercises
	Hydrotherapy
	Land-based exercise class
	Pain-relieving self-mobilizations
	Passive assisted exercises
	Scapula setting
Neural dynamics	Neural dynamics
Electro- and thermotherapies	Laser
	Interferential
	Shortwave diathermy
	Shockwave therapy
	Superficial cold
	Superficial heat
	TENS
	Ultrasound
Acupuncture and related	Acupressure
	Acupuncture
	Dry needling
	Electro-acupuncture
	Trigger-point therapy
	Deep tendon friction
	Effleurage
	Myofascial release
Taping techniques	Conventional taping
	Kinesiotaping
Immobilization	Brace
Other	Aromatherapy
	OT or combined assessment

Table 2. Consensus criteria. *“Don’t know” responses were excluded from the consensus calculations.

Definition of consensus	Consensus threshold	Implementation of intervention in UK FROST protocol	
‘Should always be used’	100%	Mandatory	
‘Should always be used’*	80%	Encouraged	Optional
—	—	—	
‘Should not be used’*	80%	Discouraged	
‘Should not be used’*	90%	Not allowed	

Table 3. Scheduling and duration of physiotherapy in the primary RCTs that showed benefit.

Study	Session length (min)	Sessions per week	Number of weeks	Sessions total
Carette	60	1	12	12
Ryans	Not reported	2	4	8

[Supplementary information](#)

Delphi results in the general context (Figures 2 to 5)

As stated in the main text, in order to apply the results more generally, consensus was re-defined as a simple majority: that is, > 50% of the valid responders who expressed an opinion. The median of responders who expressed an opinion on the stand-alone physiotherapy interventions was 95% for both the pain and stiffness predominant phases, and on the post-operative physiotherapy interventions was 98% for both the pain and stiffness predominant phases.

Stand-alone physiotherapy intervention, pain predominant phase (Figure 2) By this more liberal (> 50%) criterion, there was consensus that posture re-education, one-to-one function based exercises and one-to-one gentle active exercises 'should always be used'. (Steroid injection and manual mobilisations were pre-specified for stand-alone physiotherapy and not included in the questionnaire.) Passive assisted exercises fell short of consensus for 'should always be used', but combining this with the 'should be optional' rating revealed it to be a very acceptable intervention.

There was consensus that the majority of interventions 'should be optional'. Specifically, these included some education and re-education (CBT, explain pain and relaxation techniques); some hands-on techniques (MWMs, myofascial release, scapula-thoracic manual therapy and tool-assisted soft tissue techniques); some exercises/exercise settings (active-assisted exercises with scapula control, facilitation/strength training, gentle pulley exercises, hydrotherapy, land-based exercise class, pain-relieving self-mobilisations, PNF, proprioceptive rehabilitation and scapula setting); neural dynamics; superficial cold and heat and TENS; most acupuncture and related interventions (acupressure, acupuncture, dry needling, electro-acupuncture and trigger-point therapy); and conventional- and kinesio-taping.

Opinion on effleurage for pain was equally split between 'should be optional' and 'should not be used'.

Consensus on 'should not be used' included some forms of education and re-education (Alexander technique, graded motor imagery and mirror therapy); some hands-on techniques (craniosacral therapy and therapist-assisted end range mobilisations); one-to-one sustained stretching exercises; most electro- and thermotherapy (interferential, laser, shockwave therapy, shortwave diathermy and

ultrasound); some massage (Bowen therapy and deep friction); provision of a brace; and aromatherapy.

Stand-alone physiotherapy intervention, stiffness predominant phase (Figure 3) There was consensus that posture re-education, one-to-one function based exercises, one-to-one gentle active exercises and one-to-one sustained stretching exercises “Should always be used”. (Steroid injection and manual mobilisations were pre-specified and not included in the questionnaire.) Facilitation/strength training and active exercises with scapula control fell just short of consensus for ‘should always be used’, but combining these with their ‘should be optional’ ratings revealed them to be very acceptable interventions.

Consensus on ‘should be optional’ included some of the hands-on techniques (effleurage for pain, MWMs, myofascial release, spinal/scapula-thoracic manual therapy, tool-assisted soft-tissue techniques) and some exercises/exercise settings (gentle pulley exercises, scapula setting, hydrotherapy, land-based exercise class, PNF, therapist-assisted end-range mobilisations); superficial heat and TENS; and—alone in the ‘acupuncture and related’ group—trigger point therapy.

Consensus on interventions that ‘should not be used’ included some forms of education and re-education (Alexander technique, CBT, explain pain, graded motor imagery and mirror therapy); some hands-on techniques (Bowen therapy, craniosacral therapy and deep friction); most acupuncture and related interventions (acupuncture, acupressure, electro-acupuncture and dry needling); conventional- and kinesio-taping; most electro- and thermotherapies (interferential, laser, shockwave therapy, shortwave diathermy, superficial cold and ultrasound); provision of a brace; and aromatherapy.

Post-operative physiotherapy intervention, pain predominant phase (Figure 4)

There was consensus that one-to-one function based exercises and one-to-one gentle active exercises ‘should always be used’. Posture re-education fell just short of consensus for ‘should always be used’, but combining this with the ‘should be optional’ rating revealed it to be a very acceptable intervention.

Consensus on ‘should be optional’ included some forms of education and re-education (CBT, explain pain and relaxation techniques); some hands-on techniques (effleurage for pain and manual joint mobilisations, muscle energy techniques, MWMs, myofascial release, spinal/scapula-thoracic manual therapy, therapist-assisted end-range mobilisations and tool-assisted soft tissue techniques); some exercises/exercise

settings (active-assisted exercises with scapular control, closed chain exercises, facilitation/strength training, gentle pulley exercises, hydrotherapy, land-based exercise class, one-to-one sustained stretching exercises, passive exercises, PNF, proprioception rehabilitation and scapula setting); neural dynamics; some electro- and thermotherapy (superficial cold and heat and TENS); some acupuncture and related (acupuncture, acupressure, dry needling, electro-acupuncture, trigger point therapy); conventional- and kinesio-taping; and occupational therapy or combined assessment.

Consensus on 'should not be used' included some education and re-education (Alexander technique, graded motor imagery and mirror therapy) and hands-on techniques (Bowen therapy, craniosacral therapy and deep friction); most electrotherapies (interferential, laser, shockwave therapy, shortwave diathermy and ultrasound); and provision of a brace.

Post-operative physiotherapy intervention, stiffness predominant phase (Figure 5) There was consensus that 1-to-1 gentle active exercises, 1-to-1 function-based exercises, 1-to-1 sustained stretching exercises, active exercises with scapular control, facilitation/strength training and manual joint mobilisations 'should always be used'.

Consensus on 'should be optional' included some education and re-education (posture re-education and relaxation techniques), hands-on techniques (muscle energy techniques, MWMs, myofascial release, PNF, spinal/scapula-thoracic manual therapy, therapist-assisted end-range mobilisations and tool-assisted soft tissue techniques) and exercises (closed chain exercises, gentle pulley exercises, hydrotherapy, land-based exercise class, passive assisted exercises, proprioception rehabilitation and scapula setting); neural dynamics; superficial cold and heat; acupressure and trigger-point therapy; and occupational therapy or combined assessment.

Consensus on 'should not be used' included some education and re-education (Alexander technique, CBT, explain pain, graded motor imagery, mirror therapy), hands-on techniques (Bowen therapy, craniosacral therapy, deep friction, effleurage for pain); most electro- and thermotherapy (interferential, laser, shockwave therapy, shortwave diathermy, TENS, ultrasound), some acupuncture and related interventions (acupuncture, dry needling, electro-acupuncture); conventional- and kinesio-taping; and provision of a brace.

Structured Physiotherapy (SP) Treatment Log

Please complete this form as soon as possible after each treatment session.

Date / / Session No Duration of session (mins) Name of physiotherapist Staff grade (Please cross one box only) ☐ 5 ☐ 6 ☐ 7 ☐ ≥8How many non-surgical frozen shoulders do you treat in a typical month? (Please place a cross in one box only) ☐ 0 - 1 ☐ 2 - 3 ☐ 4 or more

Ask the patient which of the following is their main problem today. (Please place a cross in one box only and proceed as indicated.)

☐ Pain more than stiffness? ☐ Pain and stiffness equally? ☐ Stiffness more than pain?PAIN IS PREDOMINANT
Use the YELLOW columnSTIFFNESS IS PREDOMINANT
Use the GREEN column**IMPORTANT!** Interventions marked ★ ★ **must** be given as part of the overall SP package (but not necessarily at every session) unless contraindicated. Interventions marked ★ are not essential but are encouraged.

Please place a cross in the box beside any treatments given in this session. To record any treatments that are not listed, please use the free-text box provided.

Use this column if PAIN IS PREDOMINANT

- ☐ Advice and education ★ ★
- ☐ Manual shoulder mobilization ★ ★
- ☐ Home exercises (instruction/review) ★ ★
- ☐ Acupuncture, TENS or trigger-point therapy
- ☐ Hydrotherapy
- ☐ Posture correction
- ☐ Relaxation techniques
- ☐ Spinal/scapulothoracic manual therapy
- ☐ Superficial heat
- ☐ Supervised exercises (function-based)
- ☐ Supervised exercises (gentle active/self-assisted)

TREATMENTS THAT ARE NOT ALLOWED:
Brace, craniosacral therapy, deep friction, laser.

TREATMENTS THAT ARE DISCOURAGED:
Bowen therapy, shockwave therapy, ultrasound.

Use this column if STIFFNESS IS PREDOMINANT

- ☐ Advice and education ★ ★
- ☐ Manual shoulder mobilization ★ ★
- ☐ Home exercises (instruction/review) ★ ★
- ☐ Supervised exercises (function-based) ★
- ☐ Hydrotherapy
- ☐ Posture correction
- ☐ Soft-tissue techniques
- ☐ Spinal/scapulothoracic manual therapy
- ☐ Supervised exercises (active/self-assisted)
- ☐ Supervised exercises (strengthening)
- ☐ Supervised exercises (sustained stretching)

TREATMENTS THAT ARE NOT ALLOWED:
Brace, craniosacral therapy, deep friction, interferential, laser, shockwave therapy.

TREATMENTS THAT ARE DISCOURAGED:
Bowen therapy, graded motor imagery, mirror therapy, SWD, ultrasound.

Please record any other treatments given
(e.g. gym class, neural dynamics, referral to another specialty such as Occupational Therapy).Do you feel the patient has done his /her home exercises adequately? ☐ Yes ☐ NoComments:

Please record any serious adverse effects of treatment (e.g. joint infection) and notify the Research Nurse:

Please record and give reasons for any substantial deviation from the UK FROST SP Instructions (in terms of treatments given/not given, or number of sessions) and notify the Research Nurse:

Figure 6. Structured (stand-alone) physiotherapy log sheet

Post-Procedural Physiotherapy (PPP) Treatment Log

Please complete this form as soon as possible after each treatment session.

Date / / Session No Duration of session (mins)

Name of physiotherapist Staff grade (Please cross one box only) ☐ 5 ☐ 6 ☐ 7 ☐ ≥8

How many post-surgical frozen shoulders do you treat in a typical month? (Please place a cross in one box only) ☐ 0 - 1 ☐ 2 - 3 ☐ 4 or more

Ask the patient which of the following is their main problem today. (Please place a cross in one box only and proceed as indicated.)

☐ Pain more than stiffness? ☐ Pain and stiffness equally? ☐ Stiffness more than pain?

PAIN IS PREDOMINANT
Use the **YELLOW** column

STIFFNESS IS PREDOMINANT
Use the **GREEN** column

IMPORTANT! Interventions marked ★ ★ **must** be given as part of the overall PPP package (but not necessarily at every session) unless contraindicated. Interventions marked ★ are not essential but are encouraged.

Please place a cross in the box beside any treatments given in this session. To record any treatments that are not listed, please use the free-text box provided.

Use this column if **PAIN IS PREDOMINANT**

- ☐ Advice and education ★ ★
- ☐ Home exercises (instruction/review) ★ ★
- ☐ Supervised exercises (gentle active/self-assisted) ★
- ☐ Supervised exercises (function-based)
- ☐ Hydrotherapy
- ☐ Relaxation techniques
- ☐ Manual shoulder mobilization
- ☐ Superficial cold
- ☐ TENS
- ☐ Trigger point therapy
- ☐ Posture correction

TREATMENTS THAT ARE NOT ALLOWED:

Brace, deep friction, laser, shockwave therapy.

TREATMENTS THAT ARE DISCOURAGED:

Craniosacral therapy, ultrasound.

Use this column if **STIFFNESS IS PREDOMINANT**

- ☐ Advice and education ★ ★
- ☐ Home exercises (instruction/review) ★ ★
- ☐ Supervised exercises (active/self-assisted) ★
- ☐ Supervised exercises (function-based) ★
- ☐ Supervised exercises (sustained stretching)
- ☐ Supervised exercises (strengthening)
- ☐ Manual shoulder mobilization
- ☐ Soft-tissue techniques
- ☐ PNF
- ☐ Spinal/scapulothoracic manual therapy
- ☐ Posture correction

TREATMENTS THAT ARE NOT ALLOWED:

Brace, craniosacral therapy, deep friction, interferential, laser, shockwave therapy

TREATMENTS THAT ARE DISCOURAGED:

Bowen therapy, electroacupuncture, graded motor imagery, mirror therapy, SWD, ultrasound.

Please record any other treatments given
(e.g. gym class, neural dynamics, referral to another specialty such as Occupational Therapy).

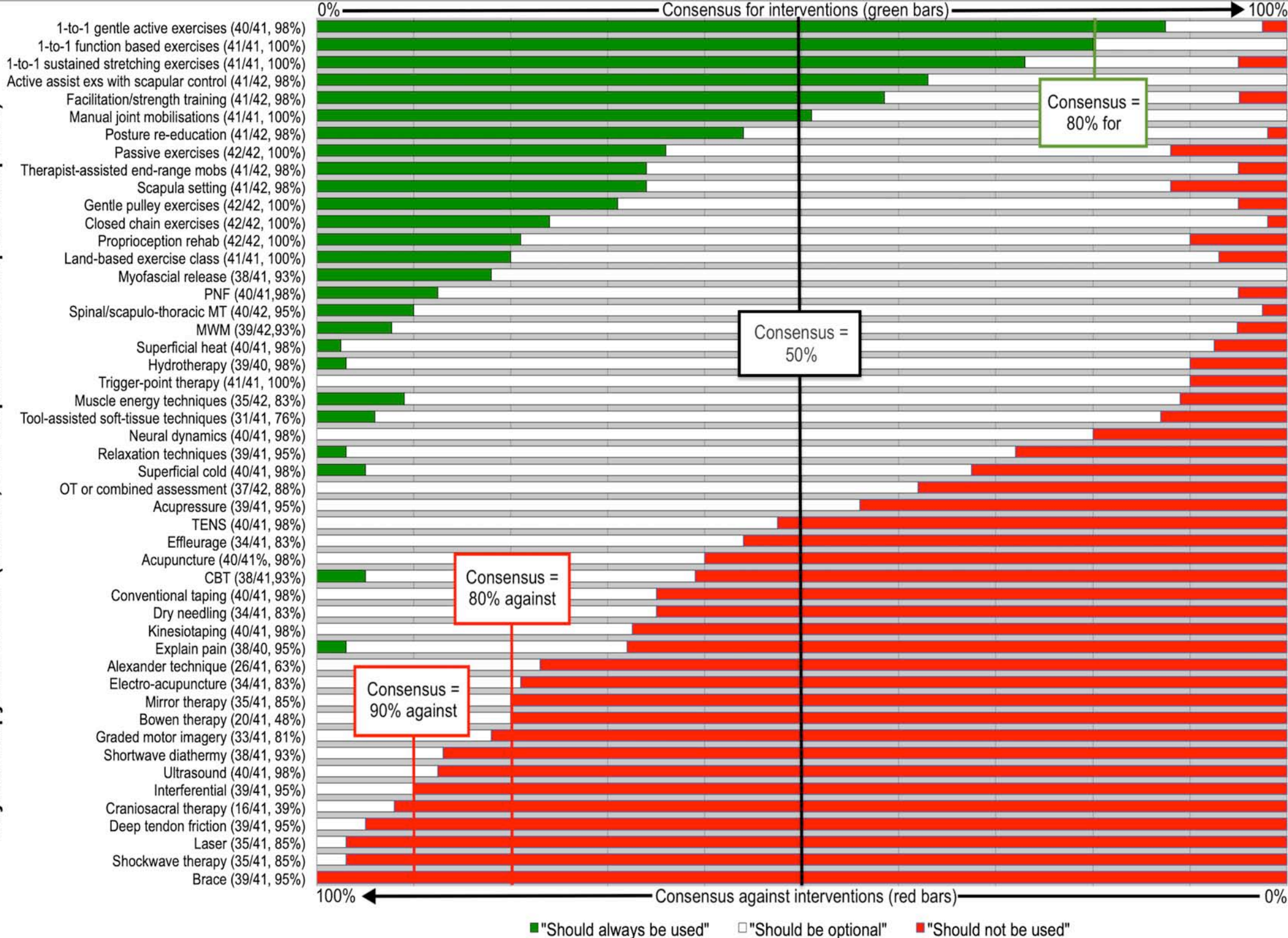
Do you feel the patient has done his /her home exercises adequately? ☐ Yes ☐ No

Comments:

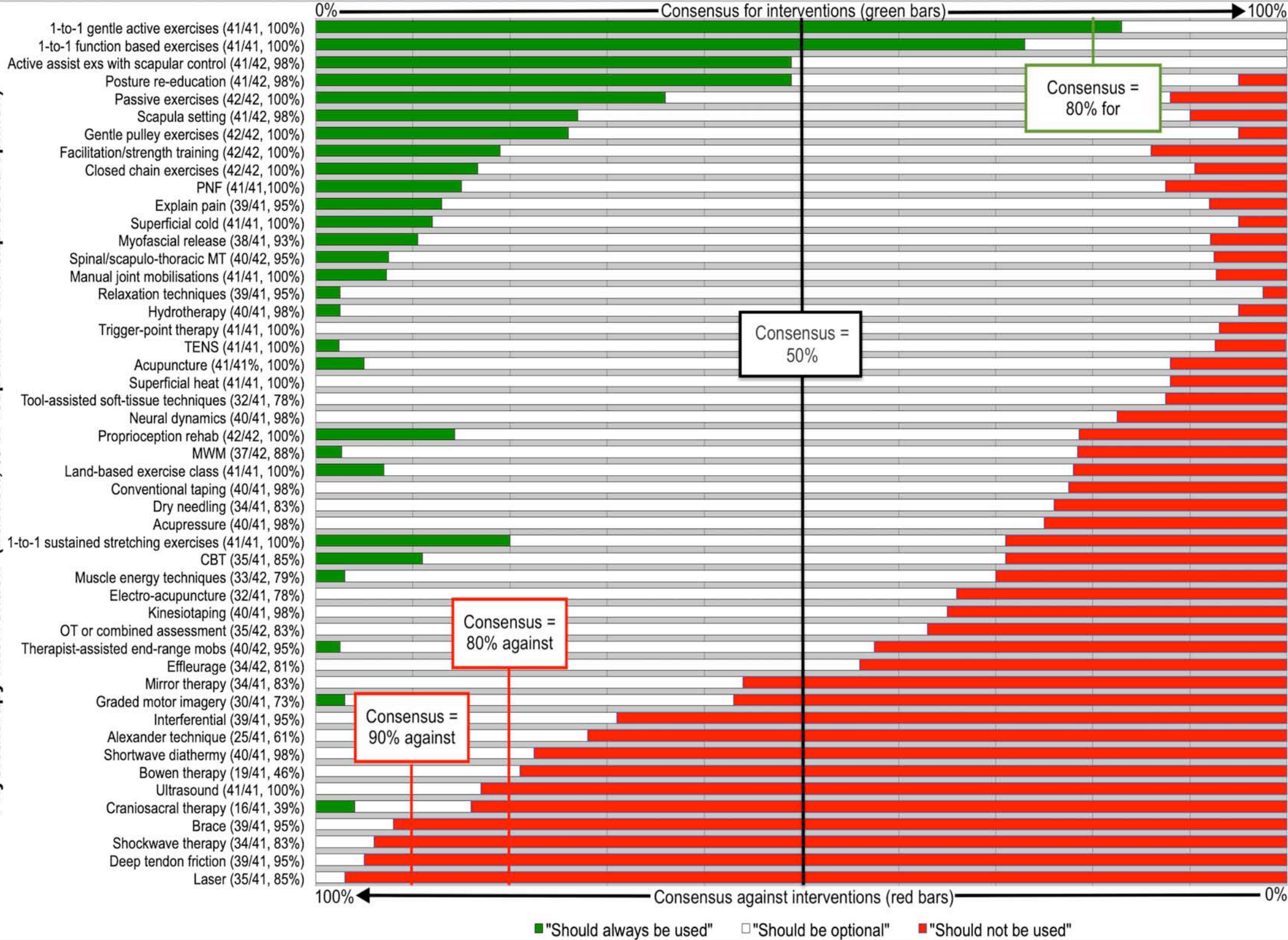
Please record any serious adverse effects of treatment, including surgery (e.g. joint infection, nerve injury), and notify the Research Nurse:

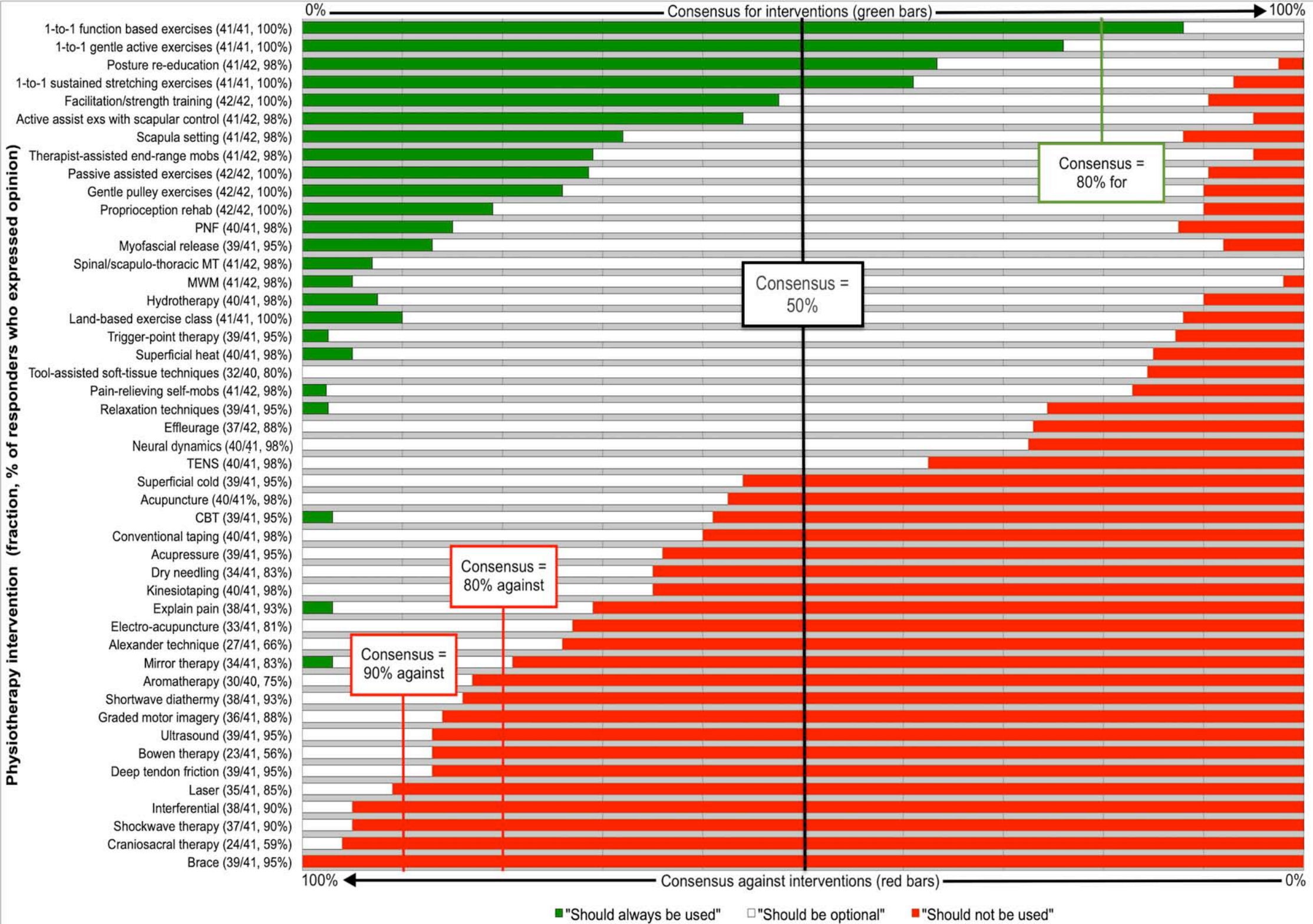
Please record and give reasons for any substantial deviation from the UK FROST PPP Instructions (in terms of treatments given/not given, or number of sessions) and notify the Research Nurse:

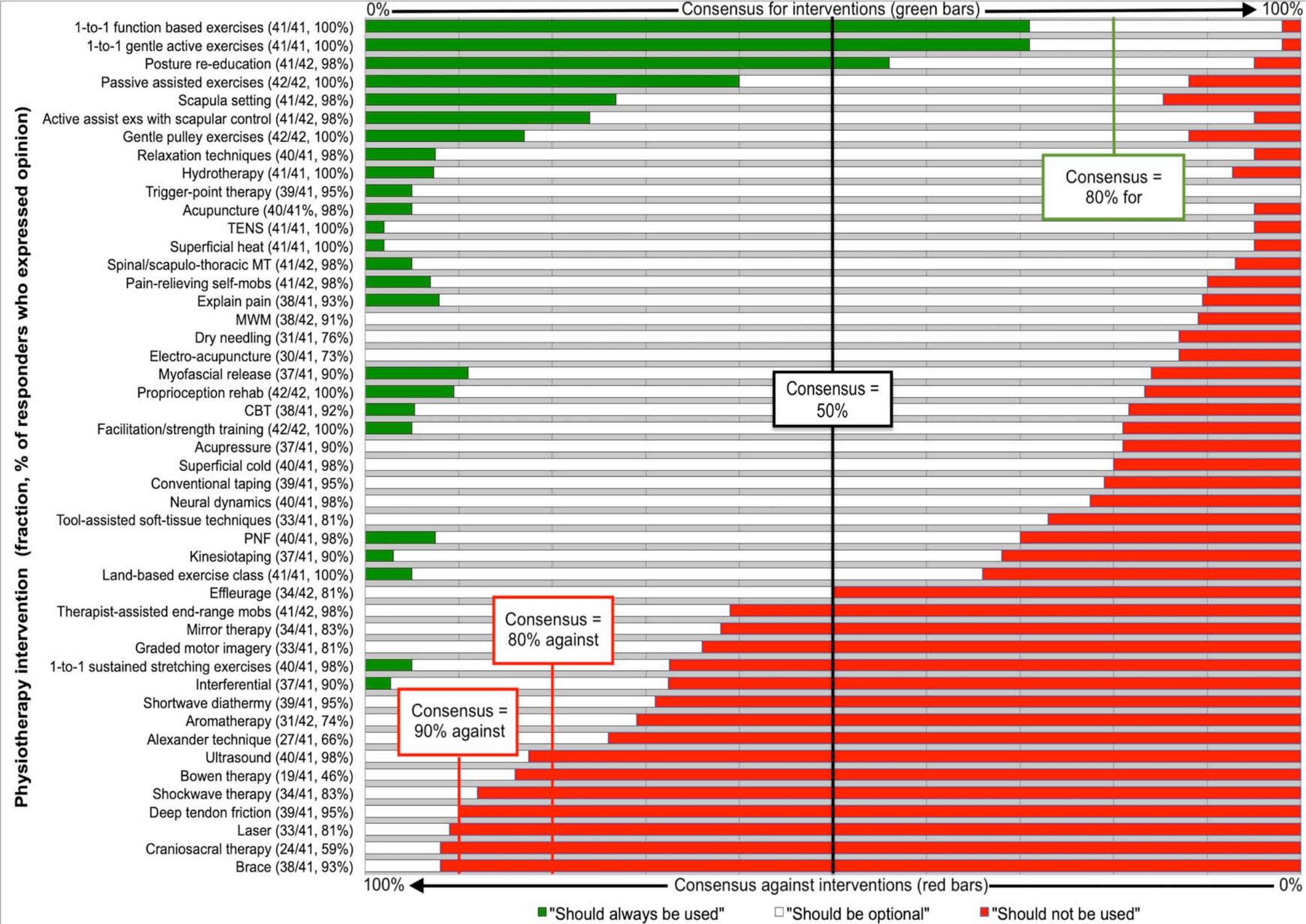
Figure 7. Post-procedural (post-operative) physiotherapy log sheet.



Physiotherapy intervention (fraction, % of responders who expressed opinion)







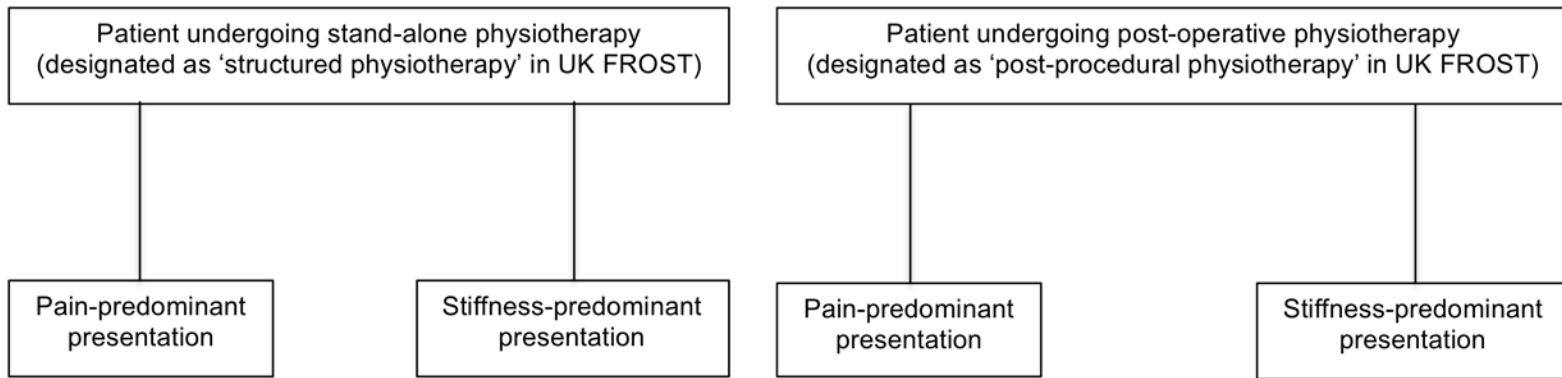


Figure 1. The four clinical contexts in UK FROST